

I U C L I D

Data Set

Existing Chemical : ID: 68411-81-4
CAS No. : 68411-81-4

Producer Related Part
Company : PCA Services, Inc.
Creation date : 28.10.2001

Substance Related Part
Company : PCA Services, Inc.
Creation date : 28.10.2001

Memo :

Printing date : 21.12.2001
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Chapter (profile) : Chapter: 1, 2, 3, 4, 5 ,6

1. General Information

Id 68411-81-4

Date 29.10.2001

1.0.1 OECD AND COMPANY INFORMATION

1.0.2 LOCATION OF PRODUCTION SITE

1.0.3 IDENTITY OF RECIPIENTS

1.1 GENERAL SUBSTANCE INFORMATION

1.1.0 DETAILS ON TEMPLATE

1.1.1 SPECTRA

1.2 SYNONYMS

2-Imidazolidinon, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methyliert
28.10.2001

2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated
28.10.2001

4,5-Dihydroxy-1,3-bis(hydroxymethyl)-2-imidazolidinone, methylated
28.10.2001

4,5-Dihydroxy-1,3-bis(hydroxymethyl)-2-imidazolidone, methylee
28.10.2001

Dihydroxydimethylolethyleneurea, methylated
28.10.2001

Dimethylolglyoxalmonoureine, methylated
28.10.2001

Dimethylolglyoxalurea, methylated
28.10.2001

Imidazolidinone-2, dihydroxy-4,5-bis(hydroxymethyl)-1,3, methylee
28.10.2001

1.3 IMPURITIES

1. General Information

Id 68411-81-4

Date 29.10.2001

1.4 ADDITIVES

1.5 QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.7 USE PATTERN

Type : industrial
Category : Textile processing industry
Reliability : (1) valid without restriction
28.10.2001

1.7.1 TECHNOLOGY PRODUCTION/USE

1.8 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.9 SOURCE OF EXPOSURE

1.10.1 RECOMMENDATIONS/PRECAUTIONARY MEASURES

1.10.2 EMERGENCY MEASURES

1.11 PACKAGING

1.12 POSSIB. OF RENDERING SUBST. HARMLESS

1.13 STATEMENTS CONCERNING WASTE

1.14.1 WATER POLLUTION

1. General Information

Id 68411-81-4

Date 29.10.2001

1.14.2 MAJOR ACCIDENT HAZARDS

1.14.3 AIR POLLUTION

1.15 ADDITIONAL REMARKS

1.16 LAST LITERATURE SEARCH

1.17 REVIEWS

1.18 LISTINGS E.G. CHEMICAL INVENTORIES

2.1 MELTING POINT

Value	: = -39 ° C
Decomposition	: no at ° C
Sublimation	: no
Method	: OECD Guide-line 102 "Melting Point/Melting Range"
Year	: 2001
GLP	: yes
Test substance	: as prescribed by 1.1 - 1.4
Result	: At room temperature the test material was clear, colored yellow, viscous and the magnetic agitator was stirring. The test material was cooled down and at about -14 degrees C the agitator stopped stirring. The cooling was continued and at about -25 degrees C the viscosity increased. The freezing point was observed between -18.5 and -19.5 degrees C. A determination of the freezing temperature with a thermocouple showed no relevant heat effect.
Test substance	: The test material (Freerez® MTH Conc.) was an aqueous concentrate of 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (present at about 84% concentration). The purity of test material or the presence of minor additives was not given. Trace levels (e.g., 0.18%) of formaldehyde may have been present.
Reliability 28.10.2001	: (1) valid without restriction.

(38)

2.2 BOILING POINT

Value	: = 118.5 ° C at 980 hPa
Decomposition	: no
Method	: OECD Guide-line 103 "Boiling Point/Boiling Range"
Year	: 2001
GLP	: yes
Test substance	: as prescribed by 1.1 - 1.4
Method	: Both a thermal analysis (using a differential scanning calorimeter) and visual tests (using a capillary tester) were employed for this determination.
Test condition	: A phase transformation, e.g., evaporation, is usually associated with a heat effect. In a preliminary study, two identical aluminum sample containers, one filled with the test material and the other empty (used as a reference), were heated in the calorimeter at a constant rate. During a preliminary experiment, the heat effect (i.e., the difference in the heat flow between the sample container and the reference container) was registered.
	<p>In the main study, a small amount of the test item was filled into two small glass tubes and boiling capillaries were inserted. The samples were heated simultaneously from 25 degrees C to about 190 degrees C. The heating rate was reduced to 10 degrees Kelvin/min. The samples were observed visually through a lens. A current stream of bubbles from the capillary indicated the boiling point. The study was performed at local atmospheric pressure (980 hPa).</p>
Result	: The Differential Scanning Calorimeter (DSC) curve of the preliminary test (heating rate of 20 degrees Kelvin/min from 25-400 degrees C) was

2. Physico-Chemical Data

Id 68411-81-4

Date 29.10.2001

recorded. An endothermic heat effect was observed starting at about 70 degrees C. As the endothermic peak was not well defined, the main study was performed using the capillary tester. After the preliminary test, the sample had lost about 70% of its mass and the residue sample was foamed and black in color. The temperature range of the endotherm was about 70-220 degrees C.

In the main test (using the capillaries and visual examination) the primary boiling range was determined to be 118.5 +-0.2 degrees C. The sample became darker while boiling but remained clear, indicating only minor decomposition.

Test substance : The test material was an aqueous concentrate of 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CAS No. 68411-81-4), present at about 84% concentration. The purity of the test material or the presence of minor additives was not given. Trace levels (e.g., 0.18%) formaldehyde may have been present.

Reliability : (1) valid without restriction.
28.10.2001

(39)

2.3 DENSITY

Value : 1.30-1.31g/ml
Method : unknown
Year :
GLP : no data
Test substance : Freerez® MTH Conc.
Reliability : (2) valid with restrictions. Manufacturer's MSDS. Method not given.
28.10.2001

(31)

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

2.5 PARTITION COEFFICIENT

Log Pow : = -3.2 at 20° C
Method : other (calculated)
Year : 2001
GLP : yes
Test substance : The test material was an aqueous concentrate of 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CAS No. 68411-81-4), present at about 84% concentration. The purity of the test material or the presence of minor additives was not given. Trace levels (e.g., 0.18%) formaldehyde may have been present.

Remark : Neither the HPLC-method according to OECD Guideline No. 117 nor the flask-shaking method according to OECD Guideline No. 107 were applicable for the determination of the partition coefficient of Freerez® MTH Conc. Thus the log Pow-value for the test item was estimated from its solubility in n-octanol and water, respectively.

2. Physico-Chemical Data

Id 68411-81-4

Date 29.10.2001

Test condition : The n-octanol solubility of the test material was determined to be < 3.25 g/l by adding 0.13-0.14 grams of test material to 40 ml n-octanol at room temperature and stirring. The result was incomplete dissolving and two phases. The water solubility of the test item was estimated to be > 5000 g/l in another study (see Section 2.6.1 below). The Log Pow was then calculated using the following equation:

Reliability : $\log \text{Pow} = \log (<3.25 \text{ g/l} / >5000 \text{ g/l}) = < -3.2$
28.10.2001 : (1) valid without restriction. (40)

2.6.1 WATER SOLUBILITY

Value : > 5000 g/l at 20 ° C
Qualitative :
Pka : at 25 ° C
PH : at and ° C
Method : OECD Guide-line 105 "Water Solubility"
Year : 2001
GLP : yes
Test substance : as prescribed by 1.1 - 1.4
Method : The water solubility of test material at room temperature was estimated by a simplified flask method.
Result : The saturated concentration was not reached, but this test indicates that the test substance is miscible in any ratio with water.
Test condition : 1 ml of water was stepwise mixed with a total amount of 5 g of Freerez® MTH Conc. This mixture was stirred at room temperature for about 24 hours. The visual observation indicated one clear, light yellow phase. The test was performed in duplicate.
Test substance : The test material (Freerez® MTH Conc.) was an aqueous concentrate of 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CAS No. 68411-81-4), present at about 84% concentration. The purity of the test material or the presence of minor additives was not given. Trace levels (e.g., 0.18%) formaldehyde may have been present.
Reliability : (1) valid without restriction
28.10.2001 (41)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2. Physico-Chemical Data

Id 68411-81-4

Date 29.10.2001

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 ADDITIONAL REMARKS

3. Environmental Fate and Pathways

Id 68411-81-4

Date 22.10.2001

3.1.1 PHOTODEGRADATION

Type	: air
Light source	: Sun light
Light spect.	: nm
Rel. intensity	: based on Intensity of Sunlight
Direct photolysis	
Half-life t _{1/2}	: ca. 1.8 - 1.4 hour(s)
Degradation	: % after
Quantum yield	:
Indirect photolysis	
Sensitizer	: OH
Conc. of sens.	:
Rate constant	: cm ³ /(molecule*sec)
Degradation	: % after
Deg. Product	:
Method	: other (calculated)
Year	: 2001
GLP	: not applicable
Test substance	: other TS
Result	: The hydroxyl rate constant was estimated to be from 73.2 - 94.5 E-12 cm ³ /molecule-sec. The first value is the rate constant calculated by EPIWIN for 2-imidazolidinone-4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), and the second value is the rate constant calculated for 2-imidazolidinone-4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4).
Test condition	: Photodegradation parameters were estimated using the EPIWIN/AOP Program (v1.90). This program uses an algorithm to sum up individual photodegradation rate constants for the different chemical bonds within the test substance molecule and the molecular weight. The photodegradation half-life was calculated assuming that the hydroxyl radical concentration is constant and using pseudo first order kinetics. The test substance itself could be modeled, because it does not have a precisely defined molecular structure. It is denoted to be "methylated" 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-. Therefore, the following analogous substances were modeled: 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) and 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4). These two analogs bound the test material, because it is partially to completely methylated in the 1,3 positions. Thus, the hydrolysis rate constant and the atmospheric half-life of the test material lies somewhere in between values for these parameters possessed by the non-methylated and bis methylated analogs. The values assigned to the test between the values calculated for the analogs.
Test substance	: 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) and 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4).
Reliability	: (2) valid with restrictions. Data were obtained by modeling with related chemicals

28.10.2001

3. Environmental Fate and Pathways

Id 68411-81-4

Date 22.10.2001

3.1.2 STABILITY IN WATER

Remark : Water stability for the test material cannot be calculated with EPIWIN. EPIWIN states merely that hydrolysis will occur slowly for the urea function in the molecule, but does not comment on the other functions in the molecule.

The test material is present in a proprietary mixture (Freerez® MTH Conc.) as an aqueous concentrate. Therefore it must be reasonably stable in water. There are no functional groups present in the molecule that would be expected to hydrolyze easily.

Reliability : (4) not assignable

3.1.3 STABILITY IN SOIL

3.2 MONITORING DATA

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type : fugacity model level III
Media : water - air
Air (level I) : 0
Water (level I) : 45.3
Soil (level I) : 54.6
Biota (level II / III) : .0755
Soil (level II / III) :
Method : other
Year : 2001
GLP : not applicable
Test substance : other TS
Remark : Note that the only input to the model was CAS Number 3001-61-4 of the neat substance. Measured values for melting point, boiling point and water solubility were not inputted, because these values were obtained for the commercial product (CAS No. 68411-81-4), which contains about 13% water. It is not appropriate to input these values for the neat substance corresponding to the CAS Number.

Mackay Level III Fugacity modeling was also conducted on the unmethylated CAS No.1854-26-8, with the following equilibrium concentrations in the environmental compartments:

Air: 0.00133%
Water: 42.8%
Soil: 57.1%
Sediment: 0.0638

These values are very close to those of the dimethylated material.

3. Environmental Fate and Pathways

Id 68411-81-4

Date 22.10.2001

- Result** : The Henry's Law Constants calculated by EPIWIN Henry (v3.10) for the dimethylated and non-methylated analogs of the test substance are as follows:
- 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) = $1.06\text{E}-12$.
- 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4) = $1.09\text{E}-13$.
- Based on the test substance's partial to complete methylation on the 1 and 3 positions, its Henry's Law Constant is likely to lie between the above two values.
- Test condition** : The EPIWIN Program was used to conduct MacKay Level III Fugacity modeling for the test substance. The test substance itself was not modeled, because it does not possess a precise molecular structure. The test substance is "methylated" 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- CAS No. 68411-81-4, which indicates that it is partially to completely methylated in the 1 and 3 positions. The extent of methylation is undefined for the test substance. For this reason Level III fugacity modeling was conducted for 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4). This material is completely methylated on both the 1 and 3 positions.
- Conclusion** : Given the values obtained by modeling both the unmethylated and completely methylated materials, one might conclude with reasonable confidence that the test substance partitions preferentially to water and soil. That conclusion is further supported by the test substance's miscibility with water and its moderate volatility.
- Test substance** : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) and 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4).
- Reliability** : (2) valid with restrictions. Data were obtained by modeling with a related chemical.

28.10.2001

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

- Type** : aerobic
- Inoculum** : activated sludge, industrial
- Concentration** : 400 mg/l related to DOC (Dissolved Organic Carbon) related to
- Contact time** :
- Degradation** : = 38% after 28 day

3. Environmental Fate and Pathways

Id 68411-81-4

Date 22.10.2001

Result :
Kinetic of test substance : 3 hour(s) = 5 %
1 day = 11 %
6 day = 31 %
13 day = 38 %
%
Deg. Product Method : Other: Standversuch
Year : 1980
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : No oxygen consumption; elimination probably not due to biodegradation.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(7)

Type : aerobic
Inoculum : activated sludge
Concentration : 50 mg/l related to Test substance
Contact time :
Degradation Result : > 70% after 2 month
other: biodegradable
Deg. Product Method :
other: OECD-Confirmatory-Test
Year : 1974
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), about 45 per cent solution in water.
Remark : Remark in IUCLID file states that the test report contained very few data
Reliability : (4) not assignable. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(2)

Type : aerobic
Inoculum : activated sludge, non-adapted
Concentration : 10 mg/l related to DOC (Dissolved Organic Carbon)
Degradation Result : = 60-70% after 28 days
inherently biodegradable
Kinetic : 28 day = 60-70 %
49 day = 70-80 %
Method : OECD Guide-line 301A (new version) "Ready Biodegradability: DOC Die Away Test"
Year : 1993
GLP : yes
Test substance : Fixapret CP conc. ((2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 26.1% solution in water). Purity 73.9%.
Test condition : Medium: water
Reliability : (2) valid with restrictions. Test material was a related chemical. Original

3. Environmental Fate and Pathways

Id 68411-81-4

Date 22.10.2001

reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000. Reliability code was changed from 1 to 2 due to reasons stated.

(10)

Type	:	aerobic
Inoculum	:	activated sludge, non-adapted
Concentration	:	20 mg/l related to DOC (Dissolved Organic Carbon)
Degradation	:	Ca. 27% after 8 day
Result	:	inherently biodegradable
Kinetic	:	5 day = 14%
		8 day = 20%
		58 day = 28%
Method	:	OECD Guide-line 303A "Simulation Test- Aerobic Sewage Treatment: Coupled Unit Test"
Year	:	1993
GLP	:	yes
Test substance	:	Fixapret CP conc. ((2-Imidazolidinone, 4,5-dihydroxy-1,3 bis(hydroxymethyl)- (CAS No. 1854-26-8), 26.1% solution in water). Purity 73.9%.
Test condition	:	Medium: water
Reliability	:	(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000. Reliability code was changed from 1 to 2 due to reasons stated.

(11)

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

Elimination	:	
Method	:	other
Year	:	
GLP	:	
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark	:	Due to the water solubility and the measured log Pow of the compound the potential for bioaccumulation is low.
Reliability	:	(4) not assignable. No experimental data is available. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	: static
Species	: Leuciscus idus (Fish, fresh water)
Exposure period	: 96 hour(s)
Unit	: mg/l
Analytical monitoring	: no
NOEC	: 1000
LC50	: ca. 2200
LC100	: 4640
Method	: other: Bestimmung der Wirkung von Wasserinhaltsstoffen auf Fische, DIN 38 412 Teil 15
Year	: 1982
GLP	: no
Test substance	: 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active ingredient: 40%.
Remark	: Data were provided by BASF personnel. Test concentrations are based on the material as supplied. Based on the amount of active material, the LC50 value is 880 mg/l (2200 mg/l x 40%).
Result	: None of the fish died before 24 hours. All fish exposed to 4640 and 10000 mg/l died by 24 hours. The numbers of fish exposed to 2150 mg/l that died by 48, 72 and 96 hours were 3/10, 5/10 and 5/10, respectively. None of the control fish or fish exposed to 1000 mg/l died by 96 hours. The 96-hour LC50 value was approximately 2200 mg/l. No confidence interval was calculated. The 48 hr LC50 value for the positive control was 34 mg/l, which corresponded to normal sensitivity. The pH, dissolved oxygen, and temperature readings ranged from 7.0 - 7.5, 7.6 - 8.8 mg/l, and 20 - 21 degrees C throughout the study.
Test condition	: Fish exposed to 10000 mg/l were observed to be tumbling at 4 hours. Fish exposed to 2150 mg/l were observed to be tumbling at 48 hours. Apathy was noted in this group at 72 and 96 hours. No signs of toxicity were noted in fish exposed to 1000 mg/l. Fish (7.2 - 9.4 cm, 4.2 - 8.9 g, corpulence factor of 1.0) were acclimated for approximately 3 months in a flow-through tank in tap water cleaned by active carbon, under a 16 hr light/ 8 hr dark cycle. Water was aerated with oil-free air. Ten fish were tested per condition [0, 1000, 2150, 4640, or 10000 mg/l test material or positive control (concentrations were not listed)]. Fish were loaded at 5.8 g/l test water. The volume of water in each vessel was 10 liters. The water hardness was 2.5 mmol/l (4:1Ca/Mg ratio). The pH, dissolved oxygen, and temperature were measured after 1, 24, 48, 72 and 96 hours. Fish were evaluated after 1, 4, 24, 48, 72 and 96 hours for lethality or signs of toxicity. The LC50 value was to be calculated according to the method of Finney (Probit Analysis, Cambridge University Press, 3 rd Ed., 1971). However at 96 hours, probit calculations were not possible. Therefore, the LC50 value at 96 hours was approximated from the data.
Reliability	: (2) valid with restrictions. Test material was a related chemical.

(3)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type	:	
Species	:	other aquatic arthropod: Daphnia magna Straus
Exposure period	:	48 hour(s)
Unit	:	mg/l
Analytical monitoring	:	
EC0	:	= 500
EC50	:	> 500
EC100	:	> 500
Method	:	Directive 84/449/EEC, C.2 "Acute toxicity for Daphnia"
Year	:	1988
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active ingredient: 40%.
Remark	:	Data were provided by BASF personnel. Test concentrations are based on the material as supplied. Based on 100% active material, the EC50 value is > 200 mg/l (> 500 mg/l x 40%).
Result	:	None of the organisms died or exhibited signs of toxicity. The pH and dissolved oxygen ranged from 7.4 - 8.2 and 7.1 - 9.1 mg/l throughout the study. The initial temperature was 292 degrees K.
Test condition	:	Daphnia (2-24 hours old) were exposed to 0, 62.5, 125, 250 or 500 mg/l test material (4 organisms/concentration). Five replicates were prepared per concentration. Test concentrations were made from a dilution series prepared from a stock solution of 500 mg test material/l dilution water (hardness = 2.5 mmol/l). Ten ml of the appropriate dilution was added to each test vessel. No additional water was added. The pH and dissolved oxygen were measured at 0 and 48 h, and temperature was measured at the beginning of the study. Daphnia were evaluated at 0, 3, 6, 24 and 48 hours for lethality or signs of toxicity.
Reliability	:	(2) valid with restrictions. Test material was a related chemical.

(6)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species	:	Scenedesmus subspicatus (Algae)
Endpoint	:	other: comparison of cell density at the end of test
Exposure period	:	72 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no
EC90	:	= 158.7
EC50	:	= 36.9
EC20	:	= 22.9
Method	:	other: "Algentest in Anlehnung UBA"
Year	:	1988
GLP	:	no
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 40%.
Remark	:	Data were provided by BASF personnel. Test concentrations are based on the material as supplied. Based on 100% active material, the EC50 value is 14.76 mg/l (36.9 mg/l x 40%). The test was valid, as the concentration of control cells increased by at least a factor of 16.

4. Ecotoxicity

Id 6 68411-81-4

Date 22.10.2001

Result : The percent cell density with respect to control for algae exposed to 7.81, 15.63, 31.25, 62.5, 125, 250 and 500 mg/l test material for 72 hours was 98.5, 102, 55.2, 26.4, 12.5, 3.26 and 0, respectively. The 72-hour EC50 value calculated from the concentration vs. % cell density curves was 36.9 mg/l.

Test condition : Algae were taken from a preculture with exponentially growing cells (3 days). Ten thousand cells were exposed to 0, 7.81, 15.63, 62.5, 125, 250 or 500 mg/l test material in standard OECD medium (≤ 0.6 mmol/l (Ca + Mg). Test solutions were made by serially diluting the 500 mg/l solution. Six replicates were prepared per concentration (4 inoculated and 2 uninoculated). Initial pH of the medium was 8.3 to 8.5. Temperature was maintained at 20 degrees C. Algae were illuminated at 400 – 700 nm, at an intensity of 120 Mikroeinstein/mxmxs. Algae were not shaken during the test, but were vortexed prior to analysis. Cell density after 72 hours was determined by measuring the chlorophyll a fluorescence at 695 nm after excitation with a short light impulse at 435 nm.

The cell density at each concentration with respect to that of the control was calculated and expressed as a percentage. The EC values were derived by plotting these values versus concentrations. The 95% confidence interval was not calculated.

Reliability : (2) valid with restrictions. Test material was a related chemical.

(6)

Species : *Scenedesmus subspicatus* (Algae)

Endpoint : other: comparison of cell density at the end of test

Exposure period : 96 hour(s)

Unit : mg/l

Analytical monitoring : no

EC90 : = 68.9

EC50 : = 28.4

EC20 : = 19.2

Method : other: "Algentest in Anlehnung UBA"

Year : 1988

GLP : no

Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 40%.

Remark : Data were provided by BASF personnel. Test concentrations are based on the material as supplied. Based on 100% active material, the EC50 value is 11.36 mg/l (28.4 mg/l x 40%). The test was valid, as the concentration of control cells increased by at least a factor of 16.

Result : The percent cell density with respect to control for algae exposed to 7.81, 15.63, 31.25, 62.5, 125, 250 and 500 mg/l test material for 96 hours was 86, 91.8, 40.8, 10.7, 3.79, 0.38 and -0.05, respectively. The 96-hour EC50 value calculated from the concentration vs. % cell density curves was 28.4 mg/l.

Test condition : Algae were taken from a preculture with exponentially growing cells (3 days). Ten thousand cells were exposed to 0, 7.81, 15.63, 62.5, 125, 250 or 500 mg/l test material in standard OECD medium (≤ 0.6 mmol/l (Ca + Mg). Test solutions were made by serially diluting the 500 mg/l solution. Six replicates were prepared per concentration (4 inoculated and 2 uninoculated). Initial pH of the medium was 8.3 to 8.5. Temperature was maintained at 20 degrees C. Algae were illuminated at 400 – 700 nm, at an intensity of 120 Mikroeinstein/mxmxs. Algae were not shaken during the test, but were vortexed prior to analysis. Cell density after 96 hours was

4. Ecotoxicity

Id 6 68411-81-4

Date 22.10.2001

determined by measuring the chlorophyll a fluorescence at 695 nm after excitation with a short light impulse at 435 nm.

The cell density at each concentration with respect to that of the control was calculated and expressed as a percentage. The EC values were derived by plotting these values versus concentrations. The 95% confidence interval was not calculated.

Reliability : (2) valid with restrictions. Test material was a related chemical.

(6)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

Type : aquatic
Species : activated sludge, industrial
Exposure period : 30 minute(s)
Unit : mg/l
Analytical monitoring : no data
EC50 : = 280
EC20 : = 180
EC80 : = 450
Method : other: Short term respiration test
Year : 1980
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : Effect: stimulation of respiration; highest tested concentration with <20% respiration inhibition =1995 mg/l.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(5)

Type : aquatic
Species : Pseudomonas putida (Bacteria)
Exposure period : 17 hour(s)
Unit : mg/l
Analytical monitoring :
EC10 : = 1260
EC50 : = 2200
EC90 : = 4490
Method : other: growth inhibition test according to Bringmann-Kuehn, DIN 38412/8 (draft)
Year : 1988
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 40%
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(6)

Type : aquatic

4. Ecotoxicity

Id 6 68411-81-4

Date 22.10.2001

Species : other bacteria: activated sludge, municipal
Exposure period : 30 minute(s)
Unit : mg/l
Analytical monitoring : no
EC10 : > = 1000
EC50 : > = 1000
EC90 : > = 1000
Method : OECD Guide-line 209 "Activated Sludge, Respiration Inhibition Test"
Year : 1993
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 74%.
Remark : No toxic effects were observed for highest concentration tested (1000 mg/l substance)
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(8)

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Species : Daphnia magna (Crustacea)
Endpoint : reproduction rate
Exposure period : 21 day
Unit : mg/l
Analytical monitoring : no data
NOEC : >= 100
LOEC : >= 100
Method : other: EG- Richtlinie XI/681/86
Year : 1986
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 70%.
Remark : 21 day semistatic test according to EEC guideline XI/681/86, Draft 4; test substance was tested in the range 0.2 to 100 mg/l, the dilution factor was 2. As test criteria, the reproduction and mortality of the test animals are given.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(9)

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4. Ecotoxicity

Id 6 68411-81-4

Date 22.10.2001

4.6.3 TOXICITY TO OTHER NON-MAMM. TERRESTRIAL SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5. Toxicity

Id 68411-81-4

Date 29.10.2001

5.1.1 ACUTE ORAL TOXICITY

Type : LD50
Species : rat
Strain : Fischer 344
Sex : male/female
Number of animals : 50
Vehicle : corn oil
Value : > 10000 mg/kg bw
Method : other
Year : 1981
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.4% in water, with 0.8% formaldehyde present
Remark : Pre-test for subchronic study. The LD50 value was greater than the highest dose tested. The LD50 value is for 100% neat substance.
Result : None of the animals died during the study. There were no differences in body weight gains between any groups for each sex. No gross morphologic changes were observed in any of the animals.

Wet, yellow staining on the anogenital region and dry brown material around the anus were observed in males and females treated with 640 or 10000 mg/kg. Dry yellow staining was noted in the anogenital region of females treated with 256 or 640 mg/kg. Females treated with 640 mg/kg had soft stools, and females treated with 10,000 mg/kg had red crusty material around the right eye and reddish brown staining around the left eye.

Test condition : Fischer 344 rats (35 males, 34 females) were obtained at 3-6 weeks of age. All animals were acclimated for 14 days, during which they were examined for general health by a veterinarian. One male rat was discarded due to poor health. Two rats were sex were euthanized and examined for disease and parasites (tested negative). Animals were randomly assigned to 5 groups of 5 animals/sex, and treated by gavage with 256, 640, 1600, 4000 or 10000 mg/kg test material in corn oil vehicle (20 ml/kg). They were fasted overnight before dosing. At time of dosing, rats weighed 82-125 g.

Animals were observed 1, 2 and 4.5 hours after dosing and daily thereafter for a period of 14 days. Animals were weighed just prior to treatment and at termination. At termination, animals were euthanized and the following organs were examined grossly: brain, pituitary, eyes, nasal cavity and turbinates, oral cavity, larynx and pharynx, tongue, salivary gland, Zymbal's gland, trachea, lungs and bronchi, thyroid, parathyroid, mandibular lymph node, esophagus, stomach, duodenum, jejunum, ileum, colon, cecum, rectum, heart and aorta, thymus (if present), sternum (with marrow), costochondral junction (rib), spinal cord, mammary gland, skin, liver, mesenteric lymph node, pancreas, spleen, kidney, adrenal, urinary bladder, testes with epididymis, tunica of the testis and scrotal sac, seminal vesicles, prostate, ovary, uterus, preputial or clitoral gland, thigh muscle, sciatic nerve, gross lesions, tissue masses or suspect tumors and regional lymph nodes.

5. Toxicity

Id 68411-81-4

Date 29.10.2001

Reliability : The LD50 value (with 95% confidence limits and the slope of the dose response curve) were to be calculated by the method of Thompson and Weil, as modified by Eby.
: (2) valid with restrictions. Test material was a related chemical. (20)

Type : LD50
Species : rat
Strain : other: Gassner
Sex : male/female
Number of animals : 40
Vehicle : other: tragacanth
Value : > 2880 mg/kg bw
Method : other: BASF test
Year : 1973
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 45% solution in water
Remark : LD50 value refers to 100% substance. Data were provided by BASF personnel.
Result : None of the animals died or exhibited any toxic symptoms.
Test condition : Groups of 5 animals/sex (bw 225-283 g for males and 108-205 g for females) were dosed by gavage with four doses of active test material ranging from 90 to 2880 mg/kg bw. The test material was administered as a 2-30% formulated product in tragacanth. Signs and symptoms of toxicity were recorded immediately after and several times during the day of treatment. They were then monitored twice every workday (or once on holidays) for a total of 7 days. The LD50 value and 95% confidence interval were to be determined from a graphical evaluation of the data on probability paper.
Reliability : (2) valid with restrictions. Test material was a related chemical. The animals were monitored for 7 days (rather than the recommended 14 for acute toxicity studies). (4)

Type : LD50
Species : mouse
Strain : B6C3F1
Sex : male/female
Number of animals : 50
Vehicle : corn oil
Value : > 10000 mg/kg bw
Method : other
Year : 1981
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.4% in water, with 0.8% formaldehyde present
Remark : Pre-test for subchronic study. The LD50 value was greater than the highest dose tested. The LD50 value is for 100% neat substance.

5. Toxicity

Id 68411-81-4

Date 29.10.2001

Result : One male treated with 1600 mg/kg died from days 8-14 (exact date was not stated). This animal had no gross lesions at autopsy. Average terminal body weights of animals in the groups did not appear to be difference. A mild preputial gland enlargement (bilateral) was noted in males treated with 256, 640, 1600 or 4000 mg/kg (N = 4, 3, 2, and 1, respectively). This was not considered to be related to treatment. No other morphologic changes were observed.

Test condition : A moist area around the base of the tail and soft stools were frequently observed in males and females treated with any dose (except that soft stools were not found in females treated with 256 mg/kg). No other clinical signs were noted.

: B6C3F1 mice (35 per sex) were obtained at 3-6 weeks of age. All animals were acclimated for 14 days, during which they were examined for general health by a veterinarian. Two mice were sex were euthanized and examined for disease and parasites (tested negative). Animals were randomly assigned to 5 groups of 5 animals/sex, and treated by gavage with 256, 640, 1600, 4000 or 10000 mg/kg test material in corn oil vehicle (20 ml/kg). They were fasted 5-6 hours before dosing. At time of dosing, mice weighed 16-26 g.

Animals were observed 1, 2 and 4.5 hours after dosing and daily thereafter for a period of 14 days. Animals were weighed just prior to treatment and at termination. At termination, animals were euthanized and the following organs were examined grossly: brain, pituitary, eyes, nasal cavity and turbinates, oral cavity, tongue, salivary gland, Zymbal's gland, trachea, lungs and bronchi, thyroid, parathyroid, mandibular lymph node, esophagus, stomach, duodenum, jejunum, ileum, colon, cecum, rectum, heart and aorta, thymus (if present), sternum (with marrow), costochondral junction (rib), spinal cord, mammary gland, skin, gall bladder, liver, mesenteric lymph node, pancreas, spleen, kidney, adrenal, urinary bladder, testes with epididymis, tunica of the testis and scrotal sac, seminal vesicles, prostate, ovary, uterus, thigh muscle, sciatic nerve, gross lesions, tissue masses or suspect tumors and regional lymph nodes.

The LD50 value (with 95% confidence limits and the slope of the dose response curve) was to be calculated by the method of Thompson and Weil, as modified by Eby.

Reliability : (2) valid with restrictions. Test material was a related chemical.

(19)

5.1.2 ACUTE INHALATION TOXICITY

Type : LC50
Species : rat
Strain : Fischer 344
Sex : male/female
Number of animals : 10
Exposure time : 4 hours
Value : > 3.1 mg/l
Method :
Year : 1981

5. Toxicity

Id 68411-81-4

Date 29.10.2001

GLP :
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 45% in water.
Remark : The LD50 value is for 100% neat substance.
Result : None of the animals died. Dyspnea was noted in all rats during exposure. Other signs observed during exposure were dry red matter immediately around in nose in 3/5 males and 1/5 females, and nasal discharge in 1/5 females. No signs were observed after exposure. All animals gained weight normally and had normal macroscopic pathology at necropsy.

Test condition : The nominal and analytical concentrations of the test material were 11.0 and 3.1 mg/l, respectively. The calculated equivalent aerodynamic diameter and geometric standard deviation of the test material were 1.5 microns and 1.79, respectively.
: Fischer 344 rats (50/sex) were acclimated for a period of 13 days, during which time they were examined for overall health by a veterinarian. Two animals died of unknown causes during this period. Two rats were sex were euthanized and examined for disease and parasites (tested negative). Animals were allowed free access to food and water except during exposure. Five rats per sex were randomly chosen for treatment. At time of exposure, the rats were 7 weeks old and weighed between 96 and 154 g.

Animals were exposed to an aerosol of the test material for 4 hours in a 54-liter glass chamber. Chamber ventilation air was supplied by the in-house compressed air system that was heated and humidified. Airflow was 50 L/min. Both nominal and actual exposure concentrations were measured. The aerosol particle size was determined with an Andersen 8-stage cascade impactor.

Animals were observed hourly during exposure and twice daily for a period of 14 days. Animals were weighed before exposure and at termination. At termination, animals were euthanized and the following organs were examined grossly: brain, pituitary, eyes, nasal cavity and turbinates, oral cavity, larynx and pharynx, tongue, salivary gland, Zymbal's gland, trachea, lungs and bronchi, thyroid, mandibular lymph node, esophagus, stomach, duodenum, jejunum, ileum, colon, cecum, rectum, heart and aorta, thymus (if present), sternum (with marrow), costochondral junction (rib), spinal cord, mammary gland, skin, liver, mesenteric lymph node, pancreas, spleen, kidney, adrenal, urinary bladder, testes with epididymis, tunica of the testis and scrotal sac, seminal vesicles, prostate, ovary, uterus, preputial or clitoral gland, thigh muscle, sciatic nerve, gross lesions, tissue masses or suspect tumors and regional lymph nodes.

Reliability : (2) valid with restrictions. Test material was a related chemical

(22)

Type : other: IRT
Species : rat
Strain : unknown
Sex : unknown
Number of animals : unknown
Vehicle : unknown
Exposure time : 8 hour(s)
Method : other: BASF test
Year : 1973

5. Toxicity

Id 68411-81-4

Date 29.10.2001

GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 45% solution in water (Fixapret CPN)
Result : No mortality after 8 hours of exposure to an atmosphere enriched or saturated at 20 degrees C. Mild signs of irritation of mucous membranes and dyspnea were observed.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(4)

Type : LC50
Species : mouse
Strain : B6C3F1
Sex : Male/female
Number of animals : 10
Value : > 3.0 mg/l
Exposure time : 4 hours
Method : other
Year : 1981
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 49.5% (w/v) in water.
Remark : The LD50 value is for 100% neat substance.
Result : None of the animals died. Dyspnea was noted in all mice during exposure. Other signs observed during exposure were tremors in 4/5 males and 4/5 females. No signs were observed after exposure. All animals gained weight normally and had normal macroscopic pathology at necropsy.

The nominal and analytical concentrations of the test material were 2.5 and 3.0 mg/l, respectively. The calculated equivalent aerodynamic diameter and geometric standard deviation of the test material were 1.6 microns and 1.83, respectively.

Test condition : B6C3F1 mice (50/sex) were acclimated for a period of 13 days, during which time they were examined for overall health by a veterinarian. Two mice were sex were euthanized and examined for disease and parasites (tested negative). Animals were allowed free access to food and water except during exposure. Five mice per sex were randomly chosen for treatment. At time of exposure, the mice were 8 weeks old and weighed between 16 and 23 g.

Animals were exposed to an aerosol of the test material for 4 hours in a 54-liter glass chamber. Chamber ventilation air was supplied by the in-house compressed air system that was heated and humidified. Airflow was 80 L/min. Both nominal and actual exposure concentrations were measured. The aerosol particle size was determined with an Andersen 8-stage cascade impactor.

Animals were observed hourly during exposure and twice daily for a period of 14 days. Animals were weighed before exposure and at termination. At termination, animals were euthanized and the following organs were examined grossly: brain, pituitary, eyes, nasal cavity and turbinates, oral cavity, larynx and pharynx, tongue, salivary gland, Zymbal's gland, trachea, lungs and bronchi, thyroid, mandibular lymph node, esophagus, stomach, duodenum, jejunum, ileum, colon, cecum, rectum, heart and aorta, thymus

5. Toxicity

Id 68411-81-4

Date 29.10.2001

(if present), sternum (with marrow), costochondral junction (rib), spinal cord, mammary gland, skin, liver, mesenteric lymph node, pancreas, spleen, kidney, adrenal, urinary bladder, testes with epididymis, tunica of the testis and scrotal sac, seminal vesicles, prostate, ovary, uterus, preputial or clitoral gland, thigh muscle, sciatic nerve, gross lesions, tissue masses or suspect tumors and regional lymph nodes.

Reliability : (2) valid with restrictions. Test material was a related chemical

(21)

5.1.3 ACUTE DERMAL TOXICITY

5.1.4 ACUTE TOXICITY, OTHER ROUTES

Type : LD50
Species : mouse
Strain :
Sex :
Number of animals :
Vehicle :
Route of admin. : i.p.
Exposure time :
Value : > 2880 mg/kg bw
Method : other: BASF test
Year : 1974
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), probably 45% solution in water (Fixapret CPN)
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(4)

5.2.1 SKIN IRRITATION

Species : rabbit
Concentration :
Exposure :
Exposure time :
Number of animals :
PDII :
Result : not irritating
EC classification : not irritating
Method : other: BASF-Test
Year : 1974
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 45% solution in water
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

5. Toxicity

Id 68411-81-4

Date 29.10.2001

(4)

Species : rabbit
Concentration :
Exposure :
Exposure time :
Number of animals :
PDII :
Result :
EC classification :
Method : other: according to "Marhold"
Year :
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : Effect: "severe"
Reliability : (4) not assignable. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(30)

5.2.2 EYE IRRITATION

Species : rabbit
Concentration :
Dose :
Exposure Time :
Comment :
Number of animals :
Result : not irritating
EC classification : not irritating
Method : other: BASF-Test
Year :
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 45% solution in water
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(4)

Species : rabbit
Concentration :
Dose :
Exposure Time :
Comment :
Number of animals :
Result :
EC classification :
Method : other: according to "Marhold"
Year :
GLP : no data

5. Toxicity

Id 68411-81-4

Date 29.10.2001

Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : Effect: "mild"
Reliability : (4) not assignable. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(30)

5.3 SENSITIZATION

Type : Patch-Test
Species : human
Concentration : Challenge 50%
Number of animals :
Vehicle : water
Result :
Classification :
Method : other: clinical test series
Year : 1958
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) (50% in aqueous solution)
Remark : Study is also described in Section 5.11
Result : Twenty seven out of 66 responded positively to various textile finishes and additives within 48 hr. Eight out of 24 tested with test substance gave a positive response. Six out of 8 also showed a positive reaction to formaldehyde (5% in aqueous solution).
Test condition : Thirty seven substances used in textile finishes (including the test substance) were patch-tested in 66 subjects who anamnestically and/or clinically were suspected of suffering from textile finish contact eczema.
Reliability : (2) valid with restrictions. Test material was a related chemical.

25.10.2001

(29)

Type : Patch-Test
Species : human
Concentration : Challenge 10 %
Vehicle : Petrolatum
Method : other: clinical test series
Year : 1980
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) (10 % in petrolatum) . The test materials contained some free formaldehyde (amount not specified).
Remark : The test material was not checked for autopolymerization or content of allergenic substances. The Calaroc resins are no longer available.
Result : Study is also described in Section 5.11
The Calaroc PG and PK induced a positive reaction in 3/10 and 1/10 of the subjects with allergic textile dermatitis, respectively. None responded to the Fixapret CPNS. All 15 responded to formaldehyde.
Test condition : Four hundred twenty eight eczema patients were patch tested with textile finish resins from 1970 to 1980 (including test material). Fifteen out of the

5. Toxicity

Id 68411-81-4

Date 29.10.2001

428 had allergic textile dermatitis based on history, clinical features and patch test results. Three different resins containing test material in 10% petrolatum were patch tested [Calaroc PK (43-47% aqueous solution); Calaroc PG (50% aqueous solution), and Fixapret CPNS] on ten of these subjects. Formaldehyde (2% in aqueous solution) was tested on all 15.

Reliability : (2) valid with restrictions. Test material was a related chemical.
25.10.2001 (1)(12)(17)

Type : Patch-Test
Species : human
Concentration : Challenge
Number of animals :
Vehicle : no data
Result :
Classification :
Method : other: clinical test series
Year : 1985
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8)
Remark : Study is also described in Section 5.11
Result : One patient who showed hypersensitivity to non-ironed sheets and pillow cases gave a positive response to the test substance; the patch test was negative to other textile finishes and formaldehyde.
Reliability : (2) valid with restrictions. Test material was a related chemical. Percent test material used is unknown. Original reference (16) was not consulted.
25.10.2001 (17)(16)

Type : Patch-Test
Species : human
Concentration : Challenge
Number of animals :
Vehicle : no data
Result :
Classification :
Method : other: clinical test series
Year :
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : Study is also described in Section 5.11
Result : One out of 6 subjects reacted to the test substance; none responded to formaldehyde.
Test condition : Twenty five subjects with contact dermatitis suspected to have arisen from permanent-pressed colored sheets were subjected to further clinical investigations. Patch test concentrations and further details were not given.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.
25.10.2001 (37)

5. Toxicity

Id 68411-81-4

Date 29.10.2001

Type	: Patch-Test
Species	: human
Concentration	: Challenge 4.5%
Number of animals	:
Vehicle	: water
Result	:
Classification	:
Method	: other: clinical test series
Year	:
GLP	: no data
Test substance	: 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) (4.5% in aqueous solution); Fixapret CPN
Remark	: In the 1960's the use of test material in fabrics yielded fabrics with approximately 500 ppm of free formaldehyde. Fabrics treated with the latest modified resins (as of 1998) predictably contain less than 75 ppm free formaldehyde. These levels are unlikely to cause contact allergy in formaldehyde-allergic individuals.
Result	: Study is also described in Section 5.11 All ten subjects reacted to Fixapret CPN and formaldehyde (only 2 reacted slightly). Three reacted slightly to the newer low-formaldehyde resins. One out of the three reacted slightly to the product that did not contain formaldehyde (and no other resins), another reacted to all of the low-formaldehyde resins, and the other reacted to most of the resins tested and formaldehyde.
Test condition	: Ten out of 12 subjects with known positive patch test reactions to older formaldehyde resins were patch-tested with commercial allergens, formaldehyde (1% in aqueous solution), older formaldehyde resins (including Fixapret CPN) and 6 newer, low-formaldehyde (< 200 ppm) resins (Fixapret ECO and NF (no formaldehyde), Freerez PKF, Freerez CLD, Permafresh EFR and CPD 3078-28A).
Conclusion	: New resins containing < 200 ppm of formaldehyde are less likely to cause dermatitis than older resins
Reliability	: (2) valid with restrictions. Test material was a related chemical.
25.10.2001	(35)

5.4.1 REPEATED DOSE TOXICITY

Species	: rat
Sex	: male/female
Strain	: Fischer 344
Route of admin.	: gavage
Exposure period	: 91 days
Frequency of treatment	: 5 days/week
Post obs. period	: no
Doses	: 1000; 3000; 6000 mg/kg/day
Control group	: yes, concurrent vehicle
NOAEL	: 1000 mg/kg/day
Method	: other: NTP Protocol
Year	: 1983
GLP	: yes

5. Toxicity

Id 68411-81-4

Date 29.10.2001

- Remark** : Inflammation of the nasal passages was seen in some control (5/20) and high dose animals (2/20). This was not considered to be a treatment-related finding (unlike the 14-day study described below), but rather due to the likelihood of Sendai virus infection (as noted in 10 control animals). The doses listed are based on 100% neat substance.
- Test substance** : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.4% in water, with 0.8% formaldehyde present (remainder water).
- Result** : Three males of the 6000 mg/kg/day dosage level were found dead on study day three. The cause of one of the deaths was aspiration pneumonia. The cause of death of the other animals was not determined. The males in the 6000 and 3000 mg/kg/day dosage level groups exhibited a lower mean body weight gain and had lower body weights at termination (314 +/- 18.1 g and 331 +/-27.1 g, respectively) than controls (358 +/- 31.1 g). The mean body weights of the males of the 1000 mg/kg/day dosage level and of the treated female rats were comparable to controls throughout the study.

Pharmacotoxic signs noted for male and female animals in the 3000 and 6000 mg/kg/day dosage level groups included primarily yellow discoloration of fur in the anogenital region and soft stool. In addition, male animals in the 6000 mg/kg/day dosage level group exhibited yellow discoloration of fur - abdominal region and soft stool. One male animal in the 6000 mg/kg/day dosage level group was noted for hypoactivity, decreased grasping reflex, extremities hypothermic to touch, and ataxia on study day 3. Other signs noted among rats of various dosage level groups, or controls, were considered incidental and unrelated to the test article.

No toxicologically significant organ weight changes occurred in this study. Macroscopically, one male from the 6000 mg/kg/day dosage level group was found at the post-mortem examination to have multiple yellowish linear macroscopic lesions in the right testis. Microscopically, the lesions were found to be moderate bilateral mineralization of testes. Microscopically, treatment related mild mineralization in the heart was seen in this male and another male in the 6000 mg/kg/day dosage level group. Mineralization in the testes and heart were considered to be test article-related lesions. No other macroscopic or microscopic findings were considered to be related to the test article.

- Test condition** : Ninety three male and 96 female Fischer 344 rats were acclimated for a period of 15 days before treatment. Based on daily observations and a pre-initiation health verification conducted one week prior to study initiation, 90 males and 92 females were selected for possible use on study. A gross necropsy was performed on five males and 5 females one day prior to test initiation. All rats examined were found to be disease and parasite-free. Animals were randomly allocated to 4 groups of 10 animals/sex. They were 44-51 days old at study initiation. Males weighed 104-161 g and females weighed 96-115 g. Food and water were available ad libitum.

Groups of animals were dosed with 0 (vehicle control), 1000, 3000 or 6000 mg/kg bw test material by gavage, 5 days/week for 13 weeks. Doses were given at a volume of 20 ml/kg. Animals were weighed prior to dosing, at weekly intervals, and at termination. Animals were observed daily for mortality and clinical signs of toxicity.

All survivors were euthanized on day 91 and received complete post-mortem examinations. The brain, lung, heart, thymus, liver, right testis and right kidney were weighed and relative weights (to brain and body) were

calculated. These tissues, plus the pituitary, eyes, nasal cavity and turbinates, oral cavity, larynx and pharynx, tongue, salivary gland, Zymbal's gland, trachea, thyroid, parathyroid, mandibular lymph node, esophagus, stomach, duodenum, jejunum, ileum, colon, cecum, rectum, sternum (with marrow), aorta, costochondral junction (rib), spinal cord, mammary gland, skin, mesenteric lymph node, pancreas, spleen, adrenal, urinary bladder, testes with epididymis, tunica of the testis and scrotal sac, seminal vesicles, prostate, ovary, uterus, preputial or clitoral gland, thigh muscle, blood smear, sciatic nerve, gross lesions, tissue masses or suspect tumors and regional lymph nodes were saved in neutral 10% formalin. Stained sections of all collected organs from the high dose and control animals (except the tongue, Zymbal's gland, costochondral junction (rib), skin, seminal vesicles, thigh muscle and sciatic nerve) were examined histologically. The eyes and pharynx were only examined if grossly abnormal. Histologic sections of heart and testis were examined for the low and mid-dose males.

Body and organ weight data of treated animals were compared to controls using a one-way analysis of variance, Bartlett's test for homogeneity of variances and the appropriate t-test (for unequal and equal variances) as described by Steel and Torrie. Dunnett's multiple comparison tables were used to assess significant differences at $p < 0.05$.

At study termination, serum samples from 5 rats/sex from the control groups were analyzed for the presence of antibodies to murine viruses designated by the NTP. Positive titers to both Sendai (all rats) and PVM virus (all females) were detected using a hemagglutination inhibition assay.

A chemical analysis was conducted prior to the study to determine purity. The material was stored in a tightly sealed metal drum at room temperature. The test material was diluted with deionized water to appropriate concentrations. Fresh solutions were prepared prior to study initiation and at 2 week intervals thereafter. Representative solutions were analyzed immediately after preparation at two sites [Midwest Research Institute (MRI), Kansas City, MO, and IRDC]. A sample taken from the 1000 mg/kg dosage level solution was analyzed to be 110% of the target concentration at MRI and 97% of the target concentration at IRDC. MRI stated that the test solutions would be stable for 2 weeks when stored in the dark at room temperature.

Reliability : (2) valid with restrictions. Test material was a related chemical. Food consumption was not monitored. Clinical chemistries, hematologies and urinalyses were not performed.

28.12.01

(26)

Species : rat
Sex : male/female
Strain : Fischer 344
Route of admin. : gavage
Exposure period : 14 days (12 doses)
Frequency of treatment : daily (without weekend) with 3 consecutive administrations before the end of the study
Post obs. period : no
Doses : 256; 640; 1600; 4000; 11680 mg/kg/day
Control group : yes, concurrent vehicle

5. Toxicity

Id 68411-81-4

Date 29.10.2001

NOAEL : 4000 mg/kg/day
Method : other: range-finding study for 90 day study
Year : 1981
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 49.5% in water (w/v), with 0.8 % formaldehyde present.
Remark : The doses listed are based on 100% neat substance.
Result : None of the animals died. None of the clinical signs observed (diarrhea, soft stool, red or brown crusty material around eyes, dry yellow stained anogenital region, or lacrimation) were considered to be related to administration of test material. There were no significant differences in body weights between groups.

There was a reduction in the mean absolute and relative weight of the lung in high dose males. There were no corresponding morphologic changes; therefore the decreased lung weight was considered to be incidental. Pulmonary congestion in 2 females treated with 640 mg/kg also was considered to be incidental. Trace to mild, patchy interstitial pneumonitis occurred in one control male and 3 high dose females. Microscopically, the nasal passages of high dose animals showed evidence of rhinitis (moderate in 3 males and 1 female, mild in 1 male and 2 females, and trace in 1 male and 2 females). Whereas 2 female control animals showed these inflammations on one side, all high dose animals had bilateral inflammations of the nasal passages. These findings were considered by test personnel to be treatment-related. There were no microscopic changes of the nasal cavities or any other abnormal findings in animals treated with lower doses.

Concentrations of test material found in samples containing nominal concentrations of 0, 25.6, 64.0, 160, 400 or 1168 mg/ml were 0, 28.6, 65.9, 169, 411 and 1181 mg/ml (within 0, 12, 3, 6, 3, and 1% of nominal, respectively).

Test condition : Fischer 344 rats (37 males, 36 females) were acclimated for 14 days. They were examined by a veterinarian 4 days before dosing and were considered to be healthy. Two rats were sex were euthanized one day before study initiation and examined for disease and parasites (tested negative). Groups of 5 animals/sex were selected randomly and dosed by intubation with 0 (vehicle), 256, 640, 1600, 4000 and 11680 mg/kg by gavage for 12 days (not including weekends), with 3 consecutive doses before termination. Food and water were available ad libitum. Animals were 42-29 days old and weighed 90-148 g on the first day of dosing. All doses were administered at a volume of 10.0 ml/kg. The vehicle control group received the same volume of water.

The test material was dissolved in water to the desired concentrations (except for the highest dose). New solutions were made weekly and were stored at room temperature and protected from light. On day 7, a chemical analysis was conducted to confirm the identity of the test material.

On days 1 and 2, animals were observed 5 times for signs of toxicity. After this period, they were observed once per day for toxicity and twice daily for mortality. Health was assessed at least once a week by a veterinarian. Individual body weights were taken at study initiation, on days 2 and 14, and at termination.

5. Toxicity

Id 68411-81-4

Date 29.10.2001

All animals were euthanized on day 14, and complete necropsies were conducted. Each animal was examined for external abnormalities and the external orifices were examined. Selected organs (brain, liver, kidneys, heart, lungs and bronchi, thymus) were removed and weighed. These organs, plus the pituitary, eyes, nasal cavity and turbinates, oral cavity, larynx and pharynx, tongue, salivary gland, Zymbal's gland, trachea, thyroid, parathyroid, mandibular lymph node, esophagus, stomach, duodenum, jejunum, ileum, colon, cecum, rectum, sternum (with marrow), aorta, costochondral junction (rib), spinal cord, mammary gland, skin, mesenteric lymph node, pancreas, spleen, adrenal, urinary bladder, testes with epididymis, tunica of the testis and scrotal sac, seminal vesicles, prostate, ovary, uterus, preputial or clitoral gland, thigh muscle, blood smear, sciatic nerve, gross lesions, tissue masses or suspect tumors and regional lymph nodes were examined and fixed in appropriate fixative. Stained sections of brain, pituitary, salivary gland, trachea, lungs and bronchi, thyroid, parathyroid, mandibular lymph node, esophagus, stomach, jejunum, colon, heart, thymus, sternum, aorta, mammary gland, liver, mesenteric lymph node, pancreas, spleen, kidneys, adrenal, urinary bladder, testes with epididymis, tunica of the testis and scrotal sac, prostate, and preputial or clitoral gland from controls and high dose animals were examined microscopically. Sections of nasal cavities from controls and all treated animals were also examined microscopically.

Body and organ weight data were analyzed using a one-way analysis of variance, Bartlett's test for homogeneity of variances and the appropriate t-test (for unequal and equal variances) as described by Steel and Torrie. Dunnett's multiple comparison tables were used to assess significant differences at $p < 0.05$.

Reliability : (2) valid with restrictions. Test material was a related chemical.
28.12.01

(24)

Species : mouse
Sex : male/female
Strain : B6C3F1
Route of admin. : gavage
Exposure period : 91 days
Frequency of treatment : daily (without weekend)
Post obs. period : no
Doses : 1000; 3000; 6000 mg/kg/day
Control group : yes, concurrent vehicle
NOAEL : 6000 mg/kg/day
Method : other:NTP protocol
Year : 1983
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). 41.4% in water, with 0.8% formaldehyde present (remainder water).
Remark : Interstitial pneumonic observed in 3 control and 3 high dose males was not considered to be a treatment-related finding, but rather due to the likelihood of Sendai virus infection (as noted in all control animals).
The doses listed are based on 100% neat substance.

5. Toxicity

Id 68411-81-4

Date 29.10.2001

Result

: Mortality: 1 male animal in 3000 mg/kg/day group died during the third week of treatment from a dosing accident, which initiated an abscess in the thoracic region.

Body weight gain: All dosed females showed an increased weight compared to the controls; the males of the 1000 and 6000 mg/kg/day group had the same or increased weight compared to the controls. The 6000 mg/kg/day group and controls showed no microscopically visible changes (the animals of the 1000 and 3000 mg/kg/day doses were not examined).

Males and females in the control (2/10 and 4/10, respectively) and 1000 mg/kg groups (8/10 males and 8/10 females) exhibited alopecia.

Chronic interstitial pneumonia in the control and animals of the 6000 mg/kg/day group was seen in correlation with the positive finding of the Sendai-virus.

Test condition

: Ninety five male and 91 female B6C3F1 mice were acclimated for a period of 14 days before treatment. Based on daily observations and a pre-initiation health verification conducted one week prior to study initiation, all animals were suitable for placement on the study (except 4 females whose water bottles had malfunctioned). A gross necropsy was performed on five males and 5 females one day prior to test initiation. All rats examined were found to be disease and parasite-free. Animals were randomly allocated to 4 groups of 10 animals/sex. They were 50-57 days old at study initiation. Males weighed 19.4 – 24.3 g and females weighed 16.0 – 20.8 g. Food and water were available ad libitum.

Groups of animals were dosed with 0 (vehicle control), 1000, 3000 or 6000 mg/kg bw test material by gavage, 5 days/week for 13 weeks. Animals were weighed prior to dosing, at weekly intervals, and at termination. Animals were observed daily for mortality and clinical signs of toxicity.

All survivors were euthanized on day 91 and received complete post-mortem examinations. The brain, lung, heart, thymus, liver, right testis and right kidney were weighed and relative weights (to brain and body) were calculated. These tissues, plus the pituitary, eyes, nasal cavity and turbinates, oral cavity, larynx and pharynx, tongue, salivary gland, Zymbal's gland, trachea, thyroid, parathyroid, mandibular lymph node, esophagus, stomach, duodenum, jejunum, ileum, colon, cecum, rectum, sternum (with marrow), aorta, bone marrow (femur), costochondral junction (rib), spinal cord, mammary gland, skin, gall bladder, mesenteric lymph node, pancreas, spleen, adrenal, urinary bladder, testes with epididymis, tunica of the testis and scrotal sac, seminal vesicles, prostate, ovary, uterus, thigh muscle, blood smear, sciatic nerve, gross lesions, tissue masses or suspect tumors and regional lymph nodes were saved in neutral 10% formalin. Stained sections of all collected organs from the high dose and control animals (except the larynx, tongue, Zymbal's gland, costochondral junction (rib), skin, seminal vesicles, thigh muscle and sciatic nerve) were examined histologically. The eyes and pharynx were only examined if grossly abnormal. If any lesion was thought to be related to treatment, the organ exhibiting this lesion was examined in the low and mid-dose animals.

Body and organ weight data of treated animals were compared to controls using a one-way analysis of variance, Bartlett's test for homogeneity of variances and the appropriate t-test (for unequal and equal variances) as described by Steel and Torrie. Dunnett's multiple comparison tables were used to assess significant differences at $p < 0.05$.

At study termination, serum samples from 5 mice/sex from the control groups were analyzed for the presence of antibodies to murine viruses designated by the NTP. Positive titers to both Sendai and PVM virus were detected in all mice using a hemagglutination inhibition assay.

5. Toxicity

Id 68411-81-4

Date 29.10.2001

A chemical analysis was conducted prior to the study to determine purity. The material was stored in a tightly sealed metal drum at room temperature. The test material was diluted with deionized water to appropriate concentrations. Fresh solutions were prepared prior to study initiation and at 2 week intervals thereafter. Representative solutions were analyzed immediately after preparation at two sites [Midwest Research Institute (MRI), Kansas City, MO, and IRDC]. A sample taken from the 1000 mg/kg dosage level solution was analyzed to be 110% of the target concentration at MRI and 97% of the target concentration at IRDC. MRI stated that the test solutions would be stable for 2 weeks when stored in the dark at room temperature.

Reliability : (2) valid with restrictions. Test material was a related chemical. Clinical chemistries, hematologies and urinalyses were not performed.

28.12.01

(25)

Species : mouse
Sex : male/female
Strain : B6C3F1
Route of admin. : gavage
Exposure period : 14 days (12 doses)
Frequency of treatment : daily (without weekend) with 4 consecutive administrations before the end of the study
Post obs. period : no
Doses : 256; 640; 1600; 4000; 11680 mg/kg/day
Control group : yes, concurrent vehicle
NOAEL : 11680 mg/kg/day
Method : other: range-finding study for 90 day study
Year : 1981
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). 49.5% active ingredient (w/v), with 0.8 % formaldehyde present (remainder water).
Remark : The doses listed are based on 100% neat substance.
Result : No deaths or substance-induced changes in body and organ weights, or micro- or macroscopic examinations occurred. Lung congestion was found in 2 males treated with 4000 mg/kg and an enlarged preputial gland was found in one control male. An increase in relative heart weight occurred in 4000 mg/kg males; the significance of this finding was listed as "unknown". The clinical signs that were observed (lacrimation, diarrhea, distal end of tail missing and hair loss around nose) were not considered to be related to test material.

Average concentrations of test material found in samples containing nominal concentrations of 0, 25.6, 64.0, 160, 400 or 1168 mg/ml were 0, 25.7, 67.3, 167, 409 and 1193 mg/ml (within 0, 5, 4, 2, 2, and 1% of nominal, respectively).

Test condition : B6C3F1 mice (37 per sex) were acclimated for 15 days. They were examined by a veterinarian 1 day before dosing and were considered to be healthy. Two mice were sex were euthanized one day before study initiation and examined for disease and parasites (tested negative). Groups of 5 animals/sex were selected randomly and dosed by intubation with 0 (vehicle), 256, 640, 1600, 4000 and 11680 mg/kg by gavage for 12 days (not including weekends), with 4 consecutive doses before termination. Food and water were available ad libitum. Animals were 51-58 days old and weighed 16-26 g on the first day of dosing. All doses were

administered at a volume of 10.0 ml/kg. The vehicle control group received the same volume of water.

The test material was dissolved in water to the desired concentrations (except for the highest dose). Single samples were taken from the first preparation and subjected to chemical analysis in duplicate.

On days 1 and 2, animals were observed 5 times for signs of toxicity. After this period, they were observed once per day for toxicity and twice daily for mortality. Health was assessed at least once a week by a veterinarian. Individual body weights were taken at study initiation, weeks 1, 2, and 3, and at termination.

All animals were euthanized on day 14, and complete necropsies were conducted. Each animal was examined for external abnormalities and the external orifices were examined. Selected organs (brain, liver, kidneys, heart, lungs and bronchi, thymus) were removed and weighed. These organs, plus the pituitary, eyes, nasal cavity and turbinates, oral cavity, larynx and pharynx, tongue, salivary gland, Zymbal's gland, trachea, thyroid, parathyroid, mandibular lymph node, esophagus, stomach, duodenum, jejunum, ileum, colon, cecum, rectum, sternum (with marrow), aorta, costochondral junction (rib), spinal cord, mammary gland, skin, mesenteric lymph node, pancreas, spleen, adrenal, urinary and gall bladder, testes with epididymis, tunica of the testis and scrotal sac, seminal vesicles, prostate, ovary, uterus, preputial or clitoral gland, thigh muscle, blood smear, sciatic nerve, gross lesions, tissue masses or suspect tumors and regional lymph nodes were examined and fixed in appropriate fixative. Stained sections of brain, pituitary, nasal cavities, salivary gland, trachea, lungs and bronchi, thyroid, parathyroid, mandibular lymph node, esophagus, stomach, jejunum, colon, heart, sternum, aorta, mammary gland, liver, gall bladder, mesenteric lymph node, pancreas, spleen, kidneys, adrenal, urinary bladder, testes with epididymis, tunica of the testis and scrotal sac, prostate, ovary, uterus, preputial or clitoral gland, blood smear, gross lesions, regional lymph nodes and tissue masses from controls and high dose animals were examined microscopically.

Body and organ weight data were analyzed using a one-way analysis of variance, Bartlett's test for homogeneity of variances and the appropriate t-test (for unequal and equal variances) as described by Steel and Torrie and Ostle. Dunnett's multiple comparison tables were used to assess significant differences at $p < 0.05$.

Reliability : (2) valid with restrictions. Test material was a related chemical.

(23)

5.5 GENETIC TOXICITY 'IN VITRO'

Type : Ames test
System of testing : Salmonella typhimurium TA102
Concentration : 1 - 5000 micrograms/plate (Plate incorporation test and Preincubation test);
 2 - 10000 micrograms/plate (Preincubation test)
Cytotoxic conc. :
Metabolic activation : with and without
Result : negative

5. Toxicity

Id 68411-81-4

Date 29.10.2001

Method : OECD Guide-line 471 "Genetic Toxicology: Salmonella typhimurium Reverse Mutation Assay"
Year : 1983
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : The assay was performed in three independent experiments. Experiment I was performed as plate incorporation test and experiments II and III were performed as preincubation tests.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

28.12.01

(14)

Type : Ames test
System of testing : Salmonella typhimurium strains TA98, TA100, TA1535, TA1537
Concentration : 33-10000 micrograms/plate (solvent DMSO); 333- 10000 micrograms/plate (solvent H₂O)
Cytotoxic conc. : 10000 micrograms/plate in most strains (produced slight to complete clearing of bacterial lawn depending on strain and test).
Metabolic activation : with and without
Result : equivocal
Method : other
Year : 1987
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). The analyzed purity was 41.4%. Since the test material is commercially available in water, it is likely that the majority of the impurity is water.
Remark : Because the tests with the two solvents were performed in different laboratories, it is difficult to discern whether the variable results were due to the tests being conducted in different laboratories or the use of different solvents.

It is also not known whether the test concentrations listed were corrected for test material purity. The number of metaphases per concentration that were examined was not listed.

Result

: The test was valid, as positive controls were judged to be mutagenic. A questionable result was found in 2/4 tests (DMSO solvent) in strain TA100 incubated with S9-mix from hamster. In one test, the number of mutations at 10000 mg/plate was higher than control (182 +/- 4.6 vs. 123 +/- 3.1 in control) and in another the number of mutations at 6667 and 10000 mg/plate was higher than control (196 +/- 11.3 and 222 +/- 7.4, respectively vs. 150 +/- 10.0 in control). A questionable result also was found in 1/3 tests at 3333 and 10000 micrograms/plate (DMSO solvent) in strain TA100 incubated with S9-mix from rat (200 +/- 5.9 and 199 +/- 4.9 vs. 147 +/- 11.2 in control). A weakly positive result was found in 1/3 tests (DMSO solvent) in strain TA98 incubated with S9-mix from hamster. In this test, concentrations equal to or greater than 333 mg/plate appeared to increase the rate of mutations (ranged from 54 +/- 2.6 at 1000 mg/plate to 66 +/- 7.2 at 3333 mg/plate vs. 37 +/- 6.4 in control). All other tests with test material dissolved in DMSO solvent were negative.

A positive result was obtained with test material dissolved in water in strain TA100 incubated with S-9 from hamster or rat. The test in TA100 in the absence of S-9 had a questionable result (approximately a 30% increase in mutations at 3333 and 6667 mg/plate vs. control). In both the positive tests, dose-dependent increases in the number of mutations were observed, with an approximate 3-fold increase over control at the two highest concentrations in the presence of S-9 (6667 and 10000 mg/plate). A slight reduction of the bacterial lawn was noted at 10000 mg/plate in strain TA100. A weakly positive result was found in strain TA98 incubated with test material dissolved in water in the absence of S-9, or in the presence of hamster S-9 (approximately a 2-fold increase over control at the two highest concentrations that did not produce toxicity). The test with rat S-9 in this strain had a questionable result (a slight, dose-dependent increase).

Test condition

: The test material was initially tested for toxicity to strain TA100 at the desired test concentrations. Nontoxic concentrations of test chemical (dissolved in DMSO or water), bacteria, and S-9 mix (10%) from liver of Aroclor1254-induced male rats or hamsters (or buffer) were incubated at 37 degrees C, without shaking, for 20 min. The top agar was added, and the contents of the tubes were mixed and poured onto the surface of petri dishes that contained Vogel-Bonner medium. At least 5 doses of test material were tested in triplicate. The histidine-revertant colonies were counted following 2 days of incubation. The maximum dose tested was 10 mg/plate. Concurrent solvent and positive controls (sodium azide for TA1535 and TA100, 9-aminoacridine for TA97 and TA1537, and 4-nitro-o-phenylenediamine for TA98) were run with each trial. The tests utilizing DMSO and water as the solvents were performed in different laboratories.

A chemical was judged to be mutagenic if a dose-related increase over the corresponding solvent control was seen, and was judged weakly mutagenic if a low-level dose response was seen. A trial was considered questionable if a dose-related increase was judged insufficiently high to justify a conclusion of weak mutagenicity, if only a single dose was elevated over control, or if a non dose-related increase was seen.

5. Toxicity

Id 68411-81-4

Date 29.10.2001

- Conclusion** : Test material was not mutagenic in strains TA1535 or TA1537. In the presence of S-9, approximately 50% of tests in strain TA100 were questionable in one laboratory (with test material in DMSO) and all tests were positive in the other laboratory (with test material in water). Weakly positive or questionable results were found in strain TA98 in the presence or absence of S-9 in the same laboratory that found positive results in strain TA100 (material was in water). One out of five tests in the other laboratory with strain TA98 in the presence of S-9 (and test material in DMSO) showed a weak response.
- Reliability** : (2) valid with restrictions. The test was only performed in 4 strains.

28.12.01

(32)(42)

5.6 GENETIC TOXICITY 'IN VIVO'

- Type** : Micronucleus assay
Species : mouse
Sex : male/female
Strain : NMRI
Route of admin. : gavage
Exposure period : once
Doses : 500, 1000, and 2000 (limit dose) as 75% solution in water
Result : negative
Method : OECD Guide-line 474 "Genetic Toxicology: Micronucleus Test"
Year : 1994
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Contained 1% formaldehyde.
Test condition : Positive controls received 20 or 80 g/kg cyclophosphamide. Routine sampling of bone marrow was at 24 hrs for all doses and additionally at 48 hrs for the high dose.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

28.12.01

(13)

- Type** : Drosophila SLRL test
Species : Drosophila melanogaster
Sex : male
Strain : other: Canton-S
Route of admin. : oral feed
Exposure period : 72 hours
Doses : 60000 ppm
Result : positive
Method : other
Year : 1984
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Analyzed purity was 41.4%. Since the test material is commercially available in water, it is presumed that the majority of the impurity is water.
Method : Woodruff, R.C., Mason, J.M. et al., Environ Mutagen 6, 189-202 (1984)
Remark : It is unknown if the weight of the test material was corrected for purity. The

5. Toxicity

Id 68411-81-4

Date 29.10.2001

Result	: criteria for significance are unconventional. The incidence of mutations in one control brood was high (3/1969 = 0.15%). : None of the treated animals died. The frequency of sex-linked recessive mutations in broods 1, 2, and 3 from males treated with test material was 4/2175, 6/2269, and 2/2117. One brood of controls had 3 mutations in 1969 chromosomes. Chromosomes from the 2 other control broods did not have any mutations. The total frequency of mutations in the treated group was 0.18% (vs. 0.06 in control). The substance was determined to be mutagenic in this test. The p value was not stated.
Test condition	: Males were fed test material in water (or water vehicle) for 3 days. The concentration used was measured by volume and converted to ppm by weight. Treated males were mated to Basc females for a total of 3 broods of post-meiotic and meiotic male germ cells over 7 days. A total of at least 5000 chromosomes were scored in each of the treated and control broods. Clusters were identified using the Poisson distribution and were removed before analysis. The result was considered positive if the mutant frequency exceeded 0.15% (with a p value < 0.05) or 0.1% (with a p value of < 0.01). If the treated frequency was between 0.1 and 0.15%, and the p value was between 0.1 and 0.01; or if the treated frequency was higher than 0.15%, and the p value was between 0.1 and 0.05, the test was considered equivocal.
Reliability 28.12.01	: (4) unassignable. Test conduct does not appear to be robust. (15)
Type	: Drosophila SLRL test
Species	: Drosophila melanogaster
Sex	: male
Strain	: other: Canton-S
Route of admin.	: other: injection
Exposure period	: 24 hours
Doses	: 60000 ppm
Result	: positive
Method	: other
Year	: 1984
GLP	: no
Test substance	: 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Analyzed purity was 41.4%. Since the test material is commercially available in water, it is presumed that the majority of the impurity is water.
Method	: Woodruff, R.C., Mason, J.M. et al., Environ Mutagen 6, 189-202 (1984)
Remark	: It is unknown if the weight of the test material was corrected for purity. The criteria for significance are unconventional. Fewer than 5000 control chromosomes were scored. One brood accounted for the majority of the mutations. Incidences in the 2 other treated broods were similar to controls. Standard deviations were not given.
Result	: Test material caused 3% mortality. The frequency of sex-linked recessive mutations in broods 1, 2, and 3 from males treated with test material was 6/2160, 0/2043, and 2/1653. One brood of controls had 2 mutations in 1493 chromosomes. Chromosomes from the 2 other control broods did not have any mutations. The total frequency of mutations in the treated group was 0.14% (vs. 0.05% in control). The substance was determined to be mutagenic in this test (although p values were not given).
Test conditions	: Males were injected with test material (or water vehicle). The concentration used was measured by volume and converted to ppm by weight. Treated males were mated to Basc females for a total of 3 broods of post-meiotic and meiotic male germ cells and over 7 days. A total of at

5. Toxicity

Id 68411-81-4

Date 29.10.2001

least 5000 chromosomes were scored in each of the treated and control broods. Clusters were identified using the Poisson distribution and were removed before analysis. The result was considered positive if the mutant frequency exceeded 0.15% (with a p value < 0.05) or 0.1% (with a p value of < 0.01). If the treated frequency was between 0.1 and 0.15%, and the p value was between 0.1 and 0.01; or if the treated frequency was higher than 0.15%, and the p value was between 0.1 and 0.05, the test was considered equivocal.

Reliability : (4) unassignable. Test conduct does not appear to be robust
28.12.01

(15)

Type : other: Drosophila reciprocal translocation assay
Species : Drosophila melanogaster
Sex : male
Strain : other: Canton-S
Route of admin. : oral feed
Exposure period : 72 hours
Doses : 50000 ppm
Result : negative
Method : other: part of NTP genotoxicity program
Year : 1984
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Analyzed purity was 41.4%.
Method : Woodruff, R.C., Mason, J.M. et al., Environ Mutagen 6, 189-202 (1984)
Remark : The test was performed on the most sensitive brood of male germ cells identified in the injection SLRL test above. The result was considered positive if the reciprocal translocation rate was greater than a historical range from 116,592 tests (0.0017%). At least 2 translocations out of 5000 tests were required to establish significance at the P < 0.05 level.
Result : There were no reciprocal translocations in a total of 5611 chromosomes
Reliability : (2) valid with restrictions. Whether the results have been corrected for test material purity is unknown.
28.12.01

(15)

5.7 CARCINOGENITY

5.8 TOXICITY TO REPRODUCTION

Type : other: examination of reproductive organs from 90-d repeated dose study
Species : rat
Sex : male/female
Strain : Fischer 344
Route of admin. : gavage
Exposure period : 91 d
Frequency of treatment : 5 times/week
Duration of test : 91 days
Doses : up to 6000 mg/kg/day
Control group : yes, concurrent vehicle
Method : other: NTP Guideline

5. Toxicity

Id 68411-81-4

Date 29.10.2001

Year : 1983
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.4 % in water, with 0.8% formaldehyde present (remainder water).
Remark : The doses listed are based on 100% neat substance. Additional information is located in Section 5.4
Result : Microscopic examination of sex organs (including testes, epididymis, prostate, preputial gland, uterus, ovaries, clitoral gland) gave no indication of morphological abnormalities in males treated with up to 3000 mg/kg/day and females treated with up to 6000 mg/kg/day. Macroscopically, one out of 10 males from the 6000 mg/kg/day dosage level group was found at the post-mortem examination to have multiple yellowish linear macroscopic lesions in the right testis. Microscopically, moderate bilateral mineralization of testes was also seen in this animal.
Reliability : (2) valid with restrictions. Effect on mating was not characterized. Test material was a related chemical.

28.12.01 (26)

Type : other: examination of reproductive organs from 90-d repeated dose study
Species : mouse
Sex : male/female
Strain : B6C3F1
Route of admin. : gavage
Exposure period : 91 d
Frequency of treatment : 5 times/week
Duration of test : 91 days
Doses : 6000 mg/kg/day
Control group : yes, concurrent vehicle
Method : other: NTP Guideline
Year : 1983
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.4 % in water, with 0.8% formaldehyde present (remainder water)
Remark : The doses listed are based on 100% neat substance. Additional information is located in Section 5.4
Result : Microscopic examination of sex organs (including testes, epididymis, prostate, preputial gland, uterus, ovaries, clitoral gland) gave no indication of morphological abnormalities in males and females treated with up to 6000 mg/kg/day.
Reliability : (2) valid with restrictions. Effect on mating was not characterized. Test material was a related chemical.

28.12.01 (25)

5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species : rat
Sex : female
Strain : Wistar
Route of admin. : gavage
Exposure period : Day 7-16 of pregnancy
Frequency of treatment : daily
Duration of test : 21 days

5. Toxicity

Id 68411-81-4

Date 29.10.2001

Doses	: 250; 500; 1000 mg/kg/day (64.1% test substance in water equivalent to 160, 320 and 640 mg/kg/day as 100% substance)
Control group	: yes
NOAEL Maternalt	: 640 mg/kg bw
NOAEL Teratogen	: 640 mg/kg bw
Method	: OECD Guide-line 414 "Teratogenicity"
Year	: 1998
GLP	: yes
Test substance	: 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 64% in water
Remark	: 23 mated females/group
Result	: There were no deaths during the study. No clinical signs were observed in any of the animals. Body weights and food consumption were not affected by the administration of the test compound. No compound-related effects were observed at necropsy of the animals. Gravid uterus weights, crown-rump lengths, litter size, sex ratios, fetal and transplacental weights remained unaffected by the administration of the test compound. There was no increase in the number of early or late conceptuses undergoing resorption. Morphological examination of the fetuses did not reveal any compound-related effect.
Reliability	: (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.
28.12.01	(18)

5.10 OTHER RELEVANT INFORMATION

Type	: Toxicokinetics
Test substance	: 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8)
Remark	: Patches of fabric soaked with ¹⁴ C-labelled test substance were applied to the dorsal skin of White New Zealand rabbits for 48 hours. 0.09 - 2.61% of the total ¹⁴ C labeling were retrieved in skin samples taking into consideration occlusion (1 - 1.4% after occlusive, ca. 0.1% after semi-occlusive), type of fabric and the specific perspiration of the skin. Perspiration almost doubled skin incorporation of radioactivity (ca. 2.6%) of the total dose in the cloth patches under occlusive conditions. Only < 0.02% was detectable in expired air as ¹⁴ C-CO ₂ . Only 0.001 to 0.006% of the activity was detected in muscle (back or thigh), fat, gonad, spleen, or brain. Higher levels were found in liver (0.117 - 0.205 % of dose), blood (0.058 - 0.095% at 4 hrs), and kidney (0.043- 0.070% of dose).
Reliability	: (2) valid with restrictions. Test material was a related chemical.
28.12.01	(33) (34)

Type	: Toxicokinetics
Test substance	: Dimethyloldihydroxy-ethylene-urea
Remark	: (¹⁴ C)-Dimethyloldihydroxy-ethylene-urea (¹⁴ C-DMDHEU) was stable to blood and skin (air) and was essentially unmetabolized (identity of HPLC radiograms of the composition of the test substance applied and the profile found after excretion). More than 95% of a 50 mg/kg intravenous dose to male F344 rats was excreted unchanged in the urine in 24 hr (85 % in 6 hr). Minor amounts were found in feces (2.2% in 24 hrs). Less than 0.2% was exhaled as ¹⁴ CO ₂ in 48 hrs. Tissues containing significant fractions of

5. Toxicity

Id 68411-81-4

Date 29.10.2001

the dose after 0.5 hr were skin, muscle, blood, liver and kidney. By 72 hours, less than 0.5% of the dose remained in the tissues, mainly in muscle (0.3%).

After administration by gavage, the oral absorption of ^{14}C -DMDHEU increased with increasing dose over the dose range of 500-2000 mg/kg. An average of 17% of an approximately 500 mg/kg dose, 28% of an approximately 1000 mg/kg dose and 38% of an approximately 2000 mg/kg dose was absorbed. The distribution pattern was similar to that of i.v. injection. More than 90% of the radioactivity that was recovered in the urine was excreted within 24 hr. After 72 hours, residual quantities of radioactivity (< 10 micrograms DMDHEU equivalents/g tissue) were left in most tissues (higher amounts in intestine and cecum).

Dermal absorption of ^{14}C -DMDHEU from a non-occluded dose site over 144 h exposure period was approximately 5% of the applied dose (for doses of 13 and 3.5 mg/cm²) and 1% of the applied dose (for a dose of 0.3 mg/cm²). Partial occlusion of the dose site resulted in a more than 4-fold increase in dermal absorption, probably due to increased hydration of the skin. Distribution of ^{14}C in tissues following dermal exposure was somewhat different than that observed following oral or intravenous dosing, with larger amounts of ^{14}C being found in adipose and smaller amounts in the muscles.

Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000, and SIDS initial assessment report for CAS No. 1854-26-8 9 (Reviewed at SIAM 10).

28.12.01

(28)

Type : Toxicokinetics
Test substance : Dimethyloldihydroxy-ethylene-urea (DMDHEU)
Remark : A further study was conducted in the rhesus monkey, which is according to the investigator "the model more closely resembling human skin". Fabrics (96 cm²) treated with ^{14}C -DMDHEU (prepared from ^{14}C -formaldehyde) were applied onto back skin of monkeys for 48 hours (either dry or with artificial perspiration). Even though the level of radioactivity used was low, essentially all of the ^{14}C -activity remained on the textile fabric (the level transferred to the skin was almost indistinguishable from background). An average of 0.12 microcuries of ^{14}C activity (equivalent to 0.029 %) could be detected in or on the skin lying underneath the fabric. No radioactivity (at or near background level) were detected in expired CO₂, urine, feces, blood, muscle, adipose, liver, lung, kidneys, spleen, brain and testes.
Conclusion : No appreciable penetration of test material from treated fabric was demonstrated
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(27)

5. Toxicity

Id 68411-81-4

Date 29.10.2001

5.11 EXPERIENCE WITH HUMAN EXPOSURE

Test substance : Dimethyloldihydroxy-ethylene-urea (DMDHEU)
Remark : One case of sensitization to dimethylol-dihydroxy-ethyleneurea was reported. Additional information is found in Section 5.3
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.
28.12.01 (16)

Test substance : Dimethyloldihydroxy-ethylene-urea (DMDHEU)
Remark : Thirty-seven substances which may be used in finishing textiles (including DMDHEU) were patch-tested in 66 patients who, anamnesticly and/or clinically, were suspected of suffering from a textile finish contact eczema. In 27 patients, positive patch-test reactions to various textile finishes and additives were observed after 48-hr contact. Eight out of 24 patients tested for DMDHEU gave a positive response to DMDHEU (50 % in aqueous solution). Six out of these 8 patients also showed a positive response to formaldehyde (5 % in aqueous solution).
Reliability : Additional information is found in Section 5.3
28.12.01 : (2) valid with restrictions. Test material was a related chemical. (29)

Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : Three different resins containing test material in 10% petrolatum [Calaroc PK (43-47% aqueous solution); Calaroc PG (50% aqueous solution), and Fixapret CPNS] were patch tested on ten of 15 subjects with allergic textile dermatitis. Formaldehyde (2% in aqueous solution) was tested on all 15. The Calaroc PG and PK (not currently available) induced a positive reaction in 3/10 and 1/10 of the subjects with allergic textile dermatitis, respectively. None responded to the Fixapret CPNS. All 15 responded to formaldehyde.
Reliability : Additional information is found in Section 5.3
25.10.2001 : (2) valid with restrictions. Test material was a related chemical. Formaldehyde content of the different resins was not determined. (1)(12)(17)

Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : One patient who showed hypersensitivity to non-ironed sheets and pillow cases gave a positive response to the test substance; the patch test was negative to other textile finishes and formaldehyde.
Reliability : Additional information is found in Section 5.3
25.10.2001 : (2) valid with restrictions. Test material was a related chemical. Original reference (16) was not consulted. (16)(17)

Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : One out of 6 subjects reacted to the test substance; none responded to

5. Toxicity

Id 68411-81-4

Date 29.10.2001

Test condition	: formaldehyde. Twenty five subjects with contact dermatitis suspected to have arisen from permanent-pressed colored sheets were subjected to further clinical investigations. Patch test concentrations and further details were not given.
Reliability	: Additional information is found in Section 5.3 (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.
25.10.2001	(37)
Test substance	: Dimethyloldihydroxy-ethylene-urea (DMDHEU; 4.5% in aqueous solution); Fixapret CPN
Remark	: In the 1960's the use of test material in fabrics yielded fabrics with approximately 500 ppm of free formaldehyde. Fabrics treated with the latest modified resins (as of 1998) predictably contain less than 75 ppm free formaldehyde. These levels are unlikely to cause contact allergy in formaldehyde-allergic individuals.
Result	: All ten subjects reacted to Fixapret CPN and formaldehyde (only 2 reacted slightly). Three reacted slightly to the newer low-formaldehyde resins. One out of the three reacted slightly to the product that did not contain formaldehyde (and no other resins), another reacted to all of the low-formaldehyde resins, and the other reacted to most of the resins tested and formaldehyde.
Test condition	: Ten out of 12 subjects with positive patch-test reactions to older formaldehyde resins were patch-tested with standard commercial allergens, formaldehyde (1% in aqueous solution), test substance (4.5% in aqueous solution), and 6 resins with low formaldehyde content (< 200 ppm).
Conclusion	: Additional information is found in Section 5.3 New resins containing < 200 ppm of formaldehyde are less likely to cause dermatitis than older resins
Reliability	: (2) valid with restrictions. Test material was a related chemical.
25.10.2001	(35)
Test substance	: Dimethyloldihydroxy-ethylene-urea (DMDHEU)
Remark	: Case report of a 10-year-old boy with eczema on both shins wearing protective shin pads. He was patch tested with a standard series and a textile series. He showed positive reactions to DMDHEU (+/+, 4.5% in aqueous), formaldehyde (++/++), the formaldehyde releasing preservatives quaternium 15 ++/++ and imidazolidinyl urea (++/++), carba mix (+), dimethylol propylene urea (+/+), tetramethylol acetylenediurea (+/+), ethylene urea melaminie-formaldehyde resin (++/++ , 5%), urea-formaldehyde resin 10% pet (++/++) and the epoxy hardener hexamethylenetetramine . He did not react to the sample of his shin pads.
Reliability	: (2) valid with restrictions. Test material was a related chemical.
25.10.2001	(36)

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